Notice of Allowability	Application No.	Applicant(s)	
	09/982,093	CHERUKURI, S. RAO	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *interview of 4/12/07*.

2. ☒ The allowed claim(s) is/are *1 and 3-24 (claims are renumbered)*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *4/12/07* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

EXAMINER'S AMENDMENT

1. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 4/12/07, attorney David W. Osborne requested an extension of time for 1 MONTH(S) and authorized the Director to charge Deposit Account No. 20-0100 the required fee of $60.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

The following clean versions of claims 1, 9, 19 and 22 will replace previous versions of these claims.

Claim 1. (currently amended) A pharmaceutical product in a compressed caplet form having a diameter and length of from about 1 mm to about 7 mm each, consisting of:

a) a therapeutically-effective amount of a uniformly distributed pharmaceutical selected from the group consisting of: antibiotics, antiinfectives, cardiovascular therapeutics, gastrointestinal agents, psychotropics and mixtures thereof;

b) at least one compressible material which is sucrose;

c) at least one lubricating material in an amount of up to about 5% by weight of the product, which is magnesium stearate;

d) a binder which is povidone k30 or plasdone k29/32.

Claim 9. (Currently amended) The encapsulated product of claim 1, wherein said pharmaceutical is a gastrointestinal therapeutic.

Claim 19. (Currently amended) The encapsulated product of claim 1, wherein said pharmaceutical is a migraine therapeutic.

Claim 22. (Currently amended) The encapsulated product of claim 1, wherein said pharmaceutical is a therapeutic for the treatment of hypertension.

Marked up Version of Claims 1, 9, 19 and 22

Claim 1. (currently amended) A pharmaceutical product in a compressed [tablet or] caplet form having a diameter and length of from about 1 mm to about 7 mm each, consisting of:

a) a therapeutically-effective amount of a uniformly distributed pharmaceutical selected from the group consisting of: antibiotics, antiinfectives, cardiovascular therapeutics, gastrointestinal agents, psychotropics and mixtures thereof;

b) at least one compressible material [selected from the group consisting of calcium phosphate, compressible sugar product, celluloses, polyols, and mixtures thereof] which is sucrose;

c) at least one lubricating material in an amount of up to about 5% by weight of the product, [selected from the group consisting of fats, emulsifiers, waxes, magnesium stearate, calcium stearate, talc, starches, silicon dioxide, and mixtures thereof said product being strong enough to withstand mechanical pressure and release the pharmaceutical in the gastrointestinal tract of a subject to which the product is administered] which is magnesium stearate;

d) [at least one binder] a binder which is povidone k30 or plasdone k29/32.

Claim 9. (Currently amended) The encapsulated product of claim 1[2], wherein said pharmaceutical is a gastrointestinal therapeutic.

Claim 19. (Currently amended) The encapsulated product of claim 1[2], wherein said pharmaceutical is a migraine therapeutic.

Claim 22. (Currently amended) The encapsulated product of claim 1[2], wherein said pharmaceutical is a therapeutic for the treatment of hypertension.

Allowable Subject Matter

2. The following is an examiner's statement of reasons for allowance: The primary reasons for allowance is the limiting of the compressible material to sucrose and limiting the binder to povidone k30 or plasdone k29/32.

3. Claims 1 and 3-7 are allowable. Claims 8-24, previously withdrawn from consideration as a result of a restriction requirement, require all the limitations of an allowable claim. Pursuant to the procedures set forth in MPEP § 821.04(a), **the election requirement for a specific pharmaceutical agent, as set forth in the Office action mailed on 07/08/2002, is hereby withdrawn** and claims 8-24 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. In view of the withdrawal of the restriction requirement, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C.

121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Blessing Fubara BF
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MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER